

### **REMARKS**

Claims 1-14 are currently pending in the application. Claims 1-14 are comprised of claims 1, 2, 4, 5, 7, 12-17 and 19-21 of the Parent Application. The specification has been modified to indicate that the present application is a continuation application of U.S. Patent Application No. 10/011,262. Accordingly, no new matter has been added.

### **CLAIMS**

#### **Claim Rejections-35 U.S.C. § 102**

The Examiner rejected claims 1, 2, 7, 12-14, 16, 20 and 21 of the Parent Application under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,253,804 B1 (Safabash). Claims 1, 2, 7, 12-14, 16, 20 and 21 of the Parent Application correspond to pending claims 1, 2, 5-8, 10, 13 and 14 of the present application, respectively. Applicants respectfully traverse this rejections.

Referring to Figs. 1(a)-4 and 7, Safabash is directed to a needle safe transfer guard that safely connects and transfers fluids between a vial 12 and a reservoir 14 with a plunger 40. The transfer guard 10 includes a vial adapter 50 connected to a reservoir adapter 52 by a support structure 54. In the preferred embodiment, the support structure includes a pair of actuating arms 80 that connect the adapters 50, 52. However, the support structure 54 may also be comprised of a pair of tubes that support the adapters 50, 52 and twist relative to each other to move the adapters 50, 52 relative to each other (Figs. 17(a)-18). A filling needle 56 is fixed to the reservoir adapter 52 at a needle mount 82 and extends into a bore 100 in the vial adapter 50. The reservoir adapter 52 may alternatively be comprised of a luer-type connector 74 fixed to an alternative transfer guide 202 (Fig. 11) that is adaptable for securing to the reservoir 14. A reservoir connector 38 includes an open end that is securable to a neck 30 of the reservoir 14 and a closed planar end with a hole in its face that provides access for the needle 56 to a septum 36 of the reservoir 14. The closed, planar end of the connector 38 abuts a closed, planar surface of the reservoir adapter 52 in a working position. The reservoir connector 38 is receivable in the reservoir adapter 52 for coupling with the needle 56 to transfer fluid to or from the reservoir 14

through the needle 56. The vial adapter 50 includes a plurality of lock tabs 58 with grippers 62 that fit over a collar 24 of the vial 12 to hold the vial adapter 50 relative to the vial 12.

Referring to Figs. 1-3, 7, 8 and 12, the present invention is directed to a syringe safety device configured to form a fluid coupling between a sealed vial 12 and a syringe 24. The device includes a tubular connector 18 and a sliding joint 22 that provide a safe coupling for the transfer of fluid from the vial 12 to the syringe 24. The tubular connector 18 has opposing first and second open axial ends 18a, 18b. The first open axial end 18a is adapted to engage an end of the vial 12. The sliding joint 22 includes opposing first and second open axial ends 22a, 22b and is removably receivable in the second open axial end 18b of the tubular connector 18. A passageway 56 extends between the first and second open axial ends 22a, 22b. The first open axial end 22a is adapted to engage with an enlarged, blunt mounting end 20b of a syringe needle 20. The second open axial end 22b of the sliding joint 22 is adapted to releasably engage at least a releasable needle receiver on a distal end 32 of a barrel 27 of a conventional luer-type syringe 24 without a needle.

Claim 1 is directed to a syringe safety device and recites, *inter alia*, a tubular connector having opposing first and second open axial ends... a sliding joint received in the second open axial end of the tubular connector, the sliding joint having opposing first and second open axial ends and a passageway between the first and second open axial ends, the first open axial end being adapted to engage with an enlarged, blunt mounting end of a syringe needle.

Applicants respectfully submit that Safabash does not anticipate claim 1 of the present application. There is no teaching, suggestion or disclosure in Safabash of a tubular connector and sliding joint that both include opposing first and second open axial ends wherein the first open axial end of the sliding joint is adapted to engage with an enlarged, blunt mounting end of a syringe needle. Specifically, Safabash teaches a transfer guard 10 with first and second open axial ends and a reservoir connector 38 with one open axial end and one planar closed end with a needle receiving hole through its center. The open axial end of the reservoir connector 38 is adapted to engage an end of a vial or syringe, however, the needle 56 of the device of Safabash is permanently secured in the transfer guard 10 and is not adapted to engage with an open axial end of the reservoir connector 38. In contrast, claim 1 of the device of the present invention claims a tubular connector 18 having opposing first and second open axial ends 18a, 18b and a sliding joint 22 having opposing first and second open axial ends 22a, 22b, wherein the first open axial

end 22a of the sliding joint is adapted to engage with an enlarged, blunt mounting end 20b of a syringe needle 20 (Figs. 8 and 12). Accordingly, Safabash teaches a reservoir connector 38 or sliding joint that has a single open axial end and a closed, planar end that is not adapted to engage an enlarged, blunt mounting end of a syringe needle. Specifically, the reservoir connector 38 or sliding joint of Safabash has a blunt, planar, axial end that does not engage with any other components of the device of Safabash. The planar, blunt, axial end rests against an inner planar surface of a reservoir adapter 52 of the transfer guard of Safabash when the reservoir connector is secured to the reservoir adapter by a snap-fit between a side surface of the reservoir connector and a hole in a side surface of the reservoir adapter (see Figs. 1(a), 7 and 10).

Based on the foregoing, Applicants respectfully request that the Examiner reconsider and withdraw any rejection of claim 1, based upon anticipation by Safabash, because Safabash does not teach, suggest or disclose each and every element of claim 1 of the present invention.

Claims 2, 5-8, 10, 13 and 14 are dependent upon claim 1. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw any rejection of these claims based upon anticipation by Safabash, for the same reasons discussed above for claim 1.

#### **Claim Rejections – 35 U.S.C. § 103**

The Examiner rejected claims 4 and 5 of the Parent Application, which correspond to pending claims 3 and 4 of the present application under 35 U.S.C. § 103(a) as being obvious in view of Safabash. The Examiner argues that Safabash discloses each of the elements of claims 3 and 4 except for a sliding joint that is configured to releasably mate with the blunt mounting end of a needle. The Examiner further argues that it would have been obvious to one having ordinary skill in the art to modify Safabash to include a sliding joint that is configured to releasably mate with the blunt mounting end of a needle. Applicants respectfully traverse this rejection.

Applicants submit that even if Safabash is modified to include a sliding joint that is configured to releasably mate with a blunt mounting end of a needle, the device would not include each of the elements of independent claim 1. Specifically, as was discussed above, Safabash discloses a sliding joint or reservoir connector 38 with an open axial end and a closed, planar axial end with a central hole, while claim 1 of the present application claims a sliding joint with first and second open axial ends where the first open axial end is adapted to engage an enlarged blunt mounting end of a syringe needle.

In addition, one having ordinary skill in the art would not modify the reservoir connector 38 or sliding joint of Safabash to include first and second open axial ends. Specifically, Safabash teaches away from a reservoir connector or sliding joint with two open axial ends because the closed, planar axial end of Safabash is designed to mate with a complementary planar surface of the reservoir adapter 52 of Safabash. The reservoir connector 38 of Safabash does not include a second open axial end that is adapted to engage with a blunt, enlarged mounting end of a syringe needle because the needle is permanently secured to the transfer guard 10. Therefore, a second open axial end on the reservoir connector would complicate its construction and hinder the mating of the axial planar surfaces of the reservoir connector and the reservoir adapter. Accordingly, one having ordinary skill in the art would not remove the needle of Safabash from its permanent attachment to the transfer guard so that it could be releasably adapted to engage with a second, open axial end of the reservoir connector.

Claims 3 and 4 are dependent upon claim 1. Based upon each of the above arguments, Applicants respectfully request that the Examiner reconsider and withdraw any rejection of claims 3 and 4 based upon unpatentability over Safabash for the same reasons discussed above for claim 1.

The Examiner also rejected claims 15, 17 and 19 of the Parent Application under 35 U.S.C. § 103(a) as being unpatentable over Safabash in view of U.S. Patent No. 5,222,946 (Basnight). Claims 15, 17 and 19 of the Parent Application correspond to pending claims 9, 11 and 12 of the current application. The Examiner argues that Safabash discloses each of the elements of claims 9, 11 and 12 except for a syringe safety device and vial and/or the syringe packaged together in sealed, sterile packaging, which the Examiner argues Basnight discloses. The Examiner also argues that it would have been obvious to one having ordinary skill in the art to modify the device of Safabash in view of Basnight to construct the claimed invention of claims 9, 11 and 12. Applicants respectfully traverse this rejection.

As was discussed above, Applicants respectfully submit that claim 1 is not anticipated or obvious in view of Safabash and likewise, respectfully submit that claim 1 is not unpatentable over the combination of Safabash in view of Basnight for the same reasons discussed above. Claims 9, 11 and 12 are dependent upon claim 1. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw any rejection of claims 9, 11 and 12 based upon

Application No. Not Yet Assigned  
Reply to Office Action of April 9, 2003

unpatentability over Safabash in view of Basnigt for the same reasons discussed above for claim 1.

### CONCLUSION

In view of the foregoing Preliminary Remarks, Applicants respectfully submit that the present application, including claims 1-14 is in condition for allowance and such action is respectfully requested.

Respectfully submitted,

Paul H. Norton et al.

December 4, 2003  
(Date)

By:

Martin G. Belisario

**MARTIN G. BELISARIO**

Registration No. 32,886

**AKIN GUMP STRAUSS HAUER & FELD LLP**

One Commerce Square

2005 Market Street, Suite 2200

Philadelphia, PA 19103-7013

Telephone: 215-965-1200

**Direct Dial: 215-965-1303**

Facsimile: 215-965-1210

E-Mail: &@@akingump.com

MGB/DJB/ccr